Comparing clinical use, effectiveness, and risks across transition from fresh frozen plasma (FFP) to solvent/detergent (SD) plasma in the Netherlands

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**Indications for plasma transfusion**

- Replenishment of plasma coagulation proteins (e.g. surgery, liver disease)
- Removal of an insulting entity via plasma exchange (e.g. TTP/HUS)

<table>
<thead>
<tr>
<th>Clinical condition</th>
<th>GoR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Correction of congenital or acquired deficiencies of clotting factors (for which there is not a specific concentrate), when the PT or aPTT ratio is &gt;1.5:</td>
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<tr>
<td>- Liver disease:</td>
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<tr>
<td>- active bleeding</td>
<td>1C+</td>
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<tr>
<td>- prevention of bleeding in the case of surgery or invasive procedures</td>
<td>2C</td>
</tr>
<tr>
<td>- During treatment with vitamin K antagonists (if prothrombin complex, which is the first choice treatment, is not available):</td>
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<tr>
<td>- in the presence of major or intracranial haemorrhage</td>
<td>1C+</td>
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<td>- in preparation for surgery than cannot be delayed</td>
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<tr>
<td>- Acute disseminated intravascular coagulation with active bleeding, in association with correction of the underlying cause</td>
<td>1C+</td>
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<td>- Microvascular bleeding during massive transfusions (&gt;1 blood volume), even before the results of PT and aPTT</td>
<td>1C+</td>
</tr>
<tr>
<td>- Deficiencies of single clotting factors, in the absence of specific concentrates (e.g. of FV), in the presence of active bleeding or to prevent bleeding during an invasive procedure</td>
<td>1C+</td>
</tr>
<tr>
<td>2. Apheretic treatment of thrombotic microangiopathies (thrombotic thrombocytopenic purpura, haemolytic-uraemic syndrome, HELLP syndrome), as a replacement fluid</td>
<td>1A</td>
</tr>
<tr>
<td>3. Reconstitution of whole blood for exchange transfusions</td>
<td>2C</td>
</tr>
<tr>
<td>4. Hereditary angioedema in the case that CI-esterase inhibitor is not available</td>
<td>2C+</td>
</tr>
</tbody>
</table>

Potential side-effects of plasma transfusion

- Allergic/anaphylactic reactions
- Non-hemolytic febrile reactions
- Acute hemolytic reactions
- Delayed hemolytic reactions
- Post-transfusion bacteremia
- Transfusion Related Acute Lung Injury (TRALI)
- Transfusion Associated Circulatory Overload (TACO)
### Plasma types

#### Quarantined Fresh Frozen Plasma (Q-FFP)

- Apheresis plasma from one donor placed in quarantine for 4-6 months
- Donor screened for various diseases
- Re-tested six months later
- Plasma unit is used following clear second screen
- Plasma stored frozen up to two years

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Blood tested:
- HIV, HBV, HCV, HEV, Syphilis, HTLV-I/II (once)

Blood tested:
- HIV, HBV, HCV, Syphilis

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Plasma types

Solvent/Detergent treated pooled Plasma (SDP) – e.g. Omniplasma™

- Plasma from ~1000 donors pooled
- Pathogen reduction process performed on pool
- Pool separated into units

Blood tested:
- HIV, HBV, HCV
- Syphilis, HTLV-I/II (once)

Blood tested:
- HAV, Parvo, HEV (NAT)* (non-enveloped)

Pool separated into units

*non-enveloped
The switch

- On January 1, 2014, the Netherlands switched from FFP to SD plasma
- Expectations were a reduction in the risk of allergic reactions and TRALI
- SD plasma units are smaller than FFP units (200mL vs. ~330mL)

- Observational cohort study to compare clinical use, effectiveness, and transfusion reaction risk for the two products
- Changes in clinical use patterns with the switch to the smaller plasma units?

FROSTED study...
FROSTED study – results

*Article currently in preparation for submission to peer-reviewed journals – results to be made available following publication*
## Acknowledgements

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